SUMMARY OF SAFETY AND EFFECTIVENESS

Compliance with 513(i) of the Federal Food, Drug and Cosmetic Act

K06 0187

January 18, 2006

JUL 27 2006

1. Submitter's Information

Common/Usual Name:	DYNAMIC MULTILEAF COLLIMATOR
Proprietary Name:	TOPSLANE DMLC
Applicant Address:	Topslane International, LLC 15375 Roosevelt Blvd. Suite #300, Clearwater, FL 33760
Contact Person:	Jim Marsh, President
Telephone:	727-507-8500
Fax:	727-507-9192

2. Predicate Devices

m3 (micro-Multileaf Collimator) (K004022, K020860)

Device Classification Name:	Therapeutic X-Ray Collimator
Regulatory Class:	Class II (according to 21 CFR 892.5050)

3. Performance Standards

No applicable standards have been established by FDA under section 514 of the Food, Drug and Cosmetic Act.

4. Device Description

K060187

TOPSLANE DMLC is a dynamic multileaf collimator designed to be mounted on the various linear accelerator. It comprises multiple motorized tungsten leafs and software. By controlling each leaf to the designed position according to the treatment planning system (TPS), TOPSLANE DMLC is intended to shape the specific field, either in static or dynamic mode. TOPSLANE DMLC can perform different field shaping methods, such as Static Field Shaping, or Step and Shoot IMRT Field Shaping or Sliding Window IMRT Field Shaping.

5. Intended Use

TOPSLANE DMLC is a dynamic multileaf collimator designed to be mounted on the linear accelerator. It is intended to shape the specific fields, either in static or dynamic mode, to assist the radiation oncologist in the delivery of radiation to well-defined target volumes while sparing surrounding normal tissue and critical organs from excess radiation.

The intended use is the same as the predicate device.

6. Summary of Substantial Equivalence

This device is similar in design and construction, and has the same intended use and performance characteristics to the predicate device. It utilizes materials that are already in use in other medical devices. No new issues of safety or effectiveness are introduced by using this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 27 2006

Mr. James N. Marsh
President
TOPSLANE International. LLC
15375 Roosevelt Blvd.. Suite #300
CLEARWATER FL 33760

Re: K060187
Trade/Device Name: TOPSLANE DMLC
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE. IXI
Dated: June 16. 2006
Received: June 20. 2006

Dear Mr. Marsh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K060187

Device Name: TOPSLANE DMLC

Indications for Use:

TOPSLANE DMLC is a dynamic multileaf collimator designed to be mounted on the linear accelerator. It is intended to shape the specific fields, either in static or dynamic mode, to assist the radiation oncologist in the delivery of radiation to well-defined target volumes while sparing surrounding normal tissue and critical organs from excess radiation.

(PLEASE DO NOT WRITE BELLOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060187